

IN THE CIRCUIT COURT  
STATE OF MISSOURI  
TWENTY-SECOND JUDICIAL CIRCUIT  
(City of St. Louis)

DEBORAH KOSTEDT;  
JILL AMOS POLIFKA;  
SHARON ANDERSON;  
CATHERINE ASH;  
JANET ATKINS;  
LOUISA BAER;  
LONI BAISCH;  
EVA BANDA;  
BONNIE BARNES;  
ELIZABETH BECK;  
CHERRI BESSETTE;  
LINDA BLACKWELL;  
JILLIAN BLUE;  
MONIQUE BOUCHER;  
JO ANN BRYANT;  
CHRISTINE BYRNE;  
BEVERLY CARLSON;  
LANDA CARTER;  
DAWN CHAMNESS;  
TABITHA CLAY;  
INDABELLE CONSALVO;  
TAMMIE COOK;  
KIMBERLY COOK;  
SHELLEY CROTTY;  
CONNIE CUMMINS;  
LAURA CUTRIGHT;  
KAREN DAM;  
JENNIR DIAZ;  
SOCCORRO DIAZ-KERBEL;  
BARBARA DOUBT;  
JENNIFER FERDOCK;  
PAULA FITCH;  
JACQULINE FOULKES;  
GLORIA FULFER;  
TERESA FULP;  
BRANDY GABLE;  
JOY GOODELL;  
MARINA GUERRA;  
PEGGY GUNTER;  
PAULINE HAMBRIGHT;

Cause Number  
Division

**JURY TRIAL DEMANDED**

SHIRLEY HAYES;  
LINDA HAZELWOOD;  
DONNA HITT;  
DEBORAH HOPKINS;  
GLORY JEFFERS;  
TERRI JIMENEZ;  
SUSAN JIRSCHEFSKE;  
REBECCA KOKE;  
TERESA KUTZ;  
LISA LAGRAN;  
DEBORAH LEWIS;  
BRENDA LITTLE;  
SOPHIA MALDONADO;  
LINDA MARCHETTI ROSENBERGER;  
PATRICIA MARINO;  
MEREDITH MARTIN;  
KAREN MASSEY;  
SHARON MCCLEESE;  
CATHY MCGEE;  
ALICIA MCKINNEY;  
LISA MEALS;  
MARIA MIRANDA-CLELAND;  
KRISTEN MORRISON;  
BRENDA MOUNT;  
DONNA MOYLE;  
CATHY MYERS;  
CHERYL MYERS;  
MARY ALICE NIELSON;  
KIMBERLY PETERSON;  
KATHLEEN PUTORTI;  
MARY ANN REEVES;  
DOROTHY RESTIVO;  
CHERYL RHODES;  
HILDA RING;  
FRANCES SANCHEZ;  
KATHARINE SESMA;  
CONNIE STANTON;  
PATRICIA SZEKERES;  
KIMBERLY TERRY;  
LINDA TIDMORE;  
KAREN WEARMOUTH;  
HEATHER WELLS;  
RAINEY WIGGINS

Plaintiffs,

v.

C.R. Bard, Inc.; DOE MANUFACTURERS 1-100.

Defendants.

### **PETITION**

COME NOW Plaintiffs, DEBORAH KOSTEDT; JILL AMOS POLIFKA; SHARON ANDERSON; CATHERINE ASH; JANET ATKINS; LOUISA BAER; LONI BAISCH; EVA BANDA; BONNIE BARNES; ELIZABETH BECK; CHERRI BESSETTE; LINDA BLACKWELL; JILLIAN BLUE; MONIQUE BOUCHER, JO ANN BRYANT; CHRISTINE BYRNE; BEVERLY CARLSON; LANDA CARTER; DAWN CHAMNESS; TABITHA CLAY; INDABELLE CONSALVO; TAMMIE COOK; KIMBERLY COOK; SHELLY CROTTY; CONNIE CUMMINS; LAURA CUTRIGHT; KAREN DAM; JENNIR DIAZ; SOCCORRO DIAZ-KERBEL; BARBARA DOUBT; JENNIFER FERDOCK; PAULA FITCH, JACQUILINE FOULKES; GLORIA FULFER; TERESA FULP; BRANDY GABLE; JOY GOODELL; MARINA GUERRA; PEGGY GUNTER; PAULINE HAMBRIGHT; SHIRLEY HAYES; LINDA HAZELWOOD; DONNA HITT; DEBORAH HOPKINS; GLORY JEFFERS; TERRI JIMENEZ; SUSAN JIRSCHESKE; REBECCA KOKE; TERESA KUTZ; LISA LAGRANDE; DEBORAH LEWIS; BRENDA LITTLE; SOPHIA MALDONADO; PATRICIA MARINO; MEREDITH MARTIN; KAREN MASSEY; SHARON MCCLEESE; CATHY MCGEE; ALICIA MCKINNEY; LISA MEALS; MARIA MIRANDA-CLELAND; KRISTEN MORRISON; BRENDA MOUNT; DONNA MOYLE; CATHY MYERS; CHERYL MYERS; MARY ALICE NIELSON; KIMBERLY PETERSON; KATHLEEN PUTORTI; MARY ANN REEVES; DOROTHY RESTIVO; CHERYL RHODES; HILDA RING; LINDA MARCHETTI ROSENBERGER; FRANCES SANCHEZ; KATHARINE SESMA; CONNIE STANTON; PATRICIA SZEKERES; KIMBERLY TERRY; LINDA TIDMORE; KAREN WEARMOUTH; HEATHER WELLS; RAINEY WIGGINS by and through their undersigned counsel, and for the cause of action against C.R. Bard, Inc.; Sofradim Production SAS; and Tissue Science Laboratories Limited; DOE MANUFACTURERS 1- 100; alleging the following upon information and belief (including investigation made by and through Plaintiffs' counsel), except those allegations that pertain to Plaintiffs, which are based on personal knowledge:

### **PARTIES**

1. Plaintiff DEBORAH KOSTEDT is a natural person residing in the State of Missouri. Plaintiff DEBORAH KOSTEDT was implanted with a Bard Mesh device during surgery performed on or around January 23, 2009. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff DEBORAH KOSTEDT

began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

2. Plaintiff JILL AMOS POLIFKA is a natural person residing in the State of Wisconsin. Plaintiff JILL AMOS POLIFKA was implanted with an Align device during surgery performed on or around January 18, 2013. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff JILL AMOS POLIFKA began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

3. Plaintiff SHARON ANDERSON is a natural person residing in the State of North Carolina. Plaintiff SHARON ANDERSON was implanted with an Align device during surgery performed on or around September 4, 2008. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff SHARON ANDERSON began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

4. Plaintiff CATHERINE ASH is a natural person residing in the State of North Carolina. Plaintiff CATHERINE ASH was implanted with an Align device during surgery performed on or around May 25, 2011. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff CATHERINE ASH began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

5. Plaintiff JANET ATKINS is a natural person residing in the State of Ohio. Plaintiff JANET ATKINS was implanted with an Ajust device during surgery performed on or around May 17, 2011. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff JANET ATKINS began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

6. Plaintiff LOUISA BAER is a natural person residing in the State of Florida. Plaintiff LOUISA BAER was implanted with an Align device during surgery performed on or around May 17, 2010. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff LOUISA BAER began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

7. Plaintiff LONI BAISCH is a natural person residing in the State of California. Plaintiff LONI BAISCH was implanted with an Align device during surgery performed on or around December 11, 2012. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff LONI BAISCH began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

8. Plaintiff EVA BANDA is a natural person residing in the State of Texas. Plaintiff EVA BANDA was implanted with an Align device during surgery performed on or around November 7, 2011. The pelvic mesh device was manufactured, marketed, advertised and

promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff EVA BANDA began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

9. Plaintiff BONNIE BARNES is a natural person residing in the State of Maryland. Plaintiff BONNIE BARNES was implanted with an Align device during surgery performed on or around September 22, 2011. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff BONNIE BARNES began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

10. Plaintiff ELIZABETH BECK is a natural person residing in the State of Mississippi. Plaintiff ELIZABETH BECK was implanted with an Align device during surgery performed on or around June 21, 2010. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff ELIZABETH BECK began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

11. Plaintiff CHERRI BESSETTE is a natural person residing in the State of Rhode Island. Plaintiff CHERRI BESSETTE was implanted with an Align device during surgery performed on or around July 27, 2010. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff CHERRI BESSETTE began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort,

urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

12. Plaintiff LINDA BLACKWELL is a natural person residing in the State of Washington. Plaintiff LINDA BLACKWELL was implanted with an Align device during surgery performed on or around April 21, 2008. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff LINDA BLACKWELL began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

13. Plaintiff JILLIAN BLUE is a natural person residing in the State of North Carolina. Plaintiff JILLIAN BLUE was implanted with an Align device during surgery performed on or around January 21, 2011. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff JILLIAN BLUE began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

14. Plaintiff MONIQUE BOUCHER is a natural person residing in the State of Connecticut. Plaintiff MONIQUE BOUCHER was implanted with an Align device during surgery performed on or around December 3, 2008. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff MONIQUE BOUCHER began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

15. Plaintiff JO ANN BRYANT is a natural person residing in the State of Michigan.

Plaintiff JO ANN BRYANT was implanted with a Faslata Allograft device during surgery performed on or around May 8, 2002. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff JO ANN BRYANT began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

16. Plaintiff CHRISTINE BYRNE is a natural person residing in the State of Michigan. Plaintiff CHRISTINE BYRNE was implanted with an Ajust device during surgery performed on or around January 26, 2011. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff CHRISTINE BYRNE began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

17. Plaintiff BEVERLY CARLSON is a natural person residing in the State of Wisconsin. Plaintiff BEVERLY CARLSON was implanted with an Align device during surgery performed on or around December 14, 2010. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff BEVERLY CARLSON began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

18. Plaintiff LANDA CARTER is a natural person residing in the State of Florida. Plaintiff LANDA CARTER was implanted with an Align device during surgery performed on or around September 28, 2007. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them.

After the device was implanted, Plaintiff LANDA CARTER began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

19. Plaintiff DAWN CHAMNESS is a natural person residing in the State of Oklahoma. Plaintiff DAWN CHAMNESS was implanted with an Align device during surgery performed on or around March 8, 2010. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff DAWN CHAMNESS began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

20. Plaintiff TABITHA CLAY is a natural person residing in the State of Alabama. Plaintiff TABITHA CLAY was implanted with an Align device during surgery performed on or around June 10, 2008. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff TABITHA CLAY began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

21. Plaintiff INDABELLE CONSALVO is a natural person residing in the State of Florida. Plaintiff INDABELLE CONSALVO was implanted with an Align device during surgery performed on or around December 23, 2008. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff INDABELLE CONSALVO began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and

believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

22. Plaintiff TAMMIE COOK is a natural person residing in the State of California. Plaintiff TAMMIE COOK was implanted with an Align device during surgery performed on or around April 22, 2008. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff TAMMIE COOK began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

23. Plaintiff KIMBERLY COOK is a natural person residing in the State of Missouri. Plaintiff KIMBERLY COOK was implanted with an Alyte Mesh device during surgery performed on or around November 6, 2012. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff KIMBERLY COOK began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

24. Plaintiff SHELLEY CROTTY is a natural person residing in the State of Kentucky. Plaintiff SHELLEY CROTTY was implanted with an Align device during surgery performed on or around March 18, 2009. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff SHELLEY CROTTY began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

25. Plaintiff CONNIE CUMMINS is a natural person residing in the State of

Tennessee. Plaintiff CONNIE CUMMINS was implanted with an Ajust device during surgery performed on or around June 24, 2011. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff CONNIE CUMMINS began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

26. Plaintiff LAURA CUTRIGHT is a natural person residing in the State of Colorado. Plaintiff LAURA CUTRIGHT was implanted with an Align device during surgery performed on or around July 28, 2008. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff LAURA CUTRIGHT began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

27. Plaintiff KAREN DAM is a natural person residing in the State of North Carolina. Plaintiff KAREN DAM was implanted with an Align device during surgery performed on or around August 23, 2011. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff KAREN DAM began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

28. Plaintiff JENNIR DIAZ is a natural person residing in the State of Pennsylvania. Plaintiff JENNIR DIAZ was implanted with an Ajust device during surgery performed on or around November 17, 2011. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them.

After the device was implanted, Plaintiff JENNIR DIAZ began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

29. Plaintiff SOCORRO KERBEL DIAZ is a natural person residing in the State of Colorado. Plaintiff SOCORRO KERBEL DIAZ was implanted with an Align device during surgery performed on or around August 30, 2010. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff SOCORRO KERBEL DIAZ began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

30. Plaintiff BARBARA DOUBT is a natural person residing in the State of Missouri. Plaintiff BARBARA DOUBT was implanted with an Allograft Dura Derm device during surgery performed on or around May 26, 2004. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff BARBARA DOUBT began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

31. Plaintiff JENNIFER FERDOCK is a natural person residing in the State of New York. Plaintiff JENNIFER FERDOCK was implanted with an Align device during surgery performed on or around August 2, 2010. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff JENNIFER FERDOCK began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent

multiple corrective surgeries to remove or part of the pelvic mesh device.

32. Plaintiff PAULA FITCH is a natural person residing in the State of Tennessee. Plaintiff PAULA FITCH was implanted with a Marlex device during surgery performed on or around April 26, 2004. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff PAULA FITCH began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

33. Plaintiff JACQUILINE FOULKES is a natural person residing in the State of North Carolina. Plaintiff JACQUILINE FOULKES was implanted with an Align device during surgery performed on or around April 20, 2010. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff JACQUILINE FOULKES began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

34. Plaintiff GLORIA FULFER is a natural person residing in the State of North Carolina. Plaintiff GLORIA FULFER was implanted with an Ajut device during surgery performed on or around December 27, 2010. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff GLORIA FULFER began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

35. Plaintiff TERESA FULP is a natural person residing in the State of North Carolina. Plaintiff TERESA FULP was implanted with an Alyte Mesh device during surgery performed on

or around January 3, 2012. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff TERESA FULP began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

36. Plaintiff BRANDY GABLE is a natural person residing in the State of Pennsylvania. Plaintiff BRANDY GABLE was implanted with an Align device during surgery performed on or around April 23, 2012. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff BRANDY GABLE began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

37. Plaintiff JOY GOODELL is a natural person residing in the State of Missouri. Plaintiff JOY GOODELL was implanted with a Bard device during surgery performed on or around February 10, 2009. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff JOY GOODELL began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

38. Plaintiff MARINA GUERRA is a natural person residing in the State of Texas. Plaintiff MARINA GUERRA was implanted with an Align device during surgery performed on or around December 10, 2008. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff MARINA GUERRA began to experience severe

complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

39. Plaintiff PEGGY GUNTER is a natural person residing in the State of Georgia. Plaintiff PEGGY GUNTER was implanted with an Align device during surgery performed on or around February 14, 2011. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff PEGGY GUNTER began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

40. Plaintiff PAULINE HAMBRIGHT is a natural person residing in the State of Pennsylvania. Plaintiff PAULINE HAMBRIGHT was implanted with an Align device during surgery performed on or around March 2, 2009. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff PAULINE HAMBRIGHT began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

41. Plaintiff SHIRLEY HAYES is a natural person residing in the State of Ohio. Plaintiff SHIRLEY HAYES was implanted with an Align device during surgery performed on or around June 2, 2009. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff SHIRLEY HAYES began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple

corrective surgeries to remove or part of the pelvic mesh device.

42. Plaintiff LINDA JUNE HAZELWOOD is a natural person residing in the State of Georgia. Plaintiff LINDA JUNE HAZELWOOD was implanted with an Align device during surgery performed on or around April 7, 2009. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff LINDA JUNE HAZELWOOD began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

43. Plaintiff DONNA HITT is a natural person residing in the State of Georgia. Plaintiff DONNA HITT was implanted with an Align device during surgery performed on or around March 11, 2009. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff DONNA HITT began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

44. Plaintiff DEBORAH HOOD HOPKINS is a natural person residing in the State of Alabama. Plaintiff DEBORAH HOOD HOPKINS was implanted with a Marlex device during surgery performed on or around August 9, 2002. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff DEBORAH HOOD HOPKINS began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

45. Plaintiff GLORY JEFFERS is a natural person residing in the State of Michigan. Plaintiff GLORY JEFFERS was implanted with an Align device during surgery performed on or around November 30, 2012. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff GLORY JEFFERS began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

46. Plaintiff TERRI JIMENEZ is a natural person residing in the State of Oklahoma. Plaintiff TERRI JIMENEZ was implanted with an Align device during surgery performed on or around May 19, 2008. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff TERRI JIMENEZ began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

47. Plaintiff SUSAN JIRSCHEFSKE is a natural person residing in the State of California. Plaintiff SUSAN JIRSCHEFSKE was implanted with an Align device during surgery performed on or around December 30, 2009. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff SUSAN JIRSCHEFSKE began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

48. Plaintiff REBECCA KOKE is a natural person residing in the State of Wisconsin. Plaintiff REBECCA KOKE was implanted with an Align device during surgery performed on or around June 20, 2012. The pelvic mesh device was manufactured, marketed, advertised and

promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff REBECCA KOKE began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

49. Plaintiff TERESA KUTZ is a natural person residing in the State of Pennsylvania. Plaintiff TERESA KUTZ was implanted with an Ajust device during surgery performed on or around February 7, 2011. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff TERESA KUTZ began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

50. Plaintiff LISA LAGRAN is a natural person residing in the State of Indiana. Plaintiff LISA LAGRAN was implanted with an Align device during surgery performed on or around June 25, 2009. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff LISA LAGRAN began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

51. Plaintiff DEBORAH LEWIS is a natural person residing in the State of Illinois. Plaintiff DEBORAH LEWIS was implanted with an Align device during surgery performed on or around March 19, 2010. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff DEBORAH LEWIS began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort,

urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

52. Plaintiff BRENDA LITTLE is a natural person residing in the State of Kansas. Plaintiff BRENDA LITTLE was implanted with an Align device during surgery performed on or around August 22, 2008. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff BRENDA LITTLE began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

53. Plaintiff SOPHIA MALDONADO is a natural person residing in the State of Texas. Plaintiff SOPHIA MALDONADO was implanted with an Align device during surgery performed on or around October 18, 2011. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff SOPHIA MALDONADO began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

54. Plaintiff LINDA MARCHETTI ROSENBERGER is a natural person residing in the State of Virginia. Plaintiff LINDA MARCHETTI ROSENBERGER was implanted with a Marlex device during surgery performed on or around April 8, 2002. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff LINDA MARCHETTI ROSENBERGER began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

55. Plaintiff PATRICIA MARINO is a natural person residing in the State of North Carolina. Plaintiff PATRICIA MARINO was implanted with an Alyte Mesh device during surgery performed on or around May 22, 2013. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff PATRICIA MARINO began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

56. Plaintiff MEREDITH MARTIN is a natural person residing in the State of Ohio. Plaintiff MEREDITH MARTIN was implanted with an Avaulta device during surgery performed on or around July 14, 2009. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff MEREDITH MARTIN began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

57. Plaintiff KAREN MASSEY is a natural person residing in the State of Pennsylvania. Plaintiff KAREN MASSEY was implanted with an Ajust device during surgery performed on or around March 14, 2011. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff KAREN MASSEY began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

58. Plaintiff SHARON MCCLEESE is a natural person residing in the State of Virginia. Plaintiff SHARON MCCLEESE was implanted with a Bard Mesh Monofilament Knitted device during surgery performed on or around November 21, 2011. The pelvic mesh device was

manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff SHARON MCCLEESE began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

59. Plaintiff CATHY MCGEE is a natural person residing in the State of North Carolina. Plaintiff CATHY MCGEE was implanted with an Ajust device during surgery performed on or around February 1, 2012. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff CATHY MCGEE began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

60. Plaintiff ALICIA MCKINNEY is a natural person residing in the State of Ohio. Plaintiff ALICIA MCKINNEY was implanted with an Align device during surgery performed on or around June 19, 2008. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff ALICIA MCKINNEY began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

61. Plaintiff LISA MEALS is a natural person residing in the State of Pennsylvania. Plaintiff LISA MEALS was implanted with an Alyte Y-Mesh Graft device during surgery performed on or around April 2, 2013. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff LISA MEALS began to experience severe

complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

62. Plaintiff MARIA MIRANDA-CLELAND is a natural person residing in the State of Iowa. Plaintiff MARIA MIRANDA-CLELAND was implanted with an Ajust device during surgery performed on or around August 26, 2011. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff MARIA MIRANDA-CLELAND began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

63. Plaintiff KRISTEN MORRISON is a natural person residing in the State of Arizona. Plaintiff KRISTEN MORRISON was implanted with an Alyte Y-Mesh Graft device during surgery performed on or around September 18, 2014. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff KRISTEN MORRISON began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

64. Plaintiff BRENDA MOUNT is a natural person residing in the State of Indiana. Plaintiff BRENDA MOUNT was implanted with an Align device during surgery performed on or around December 15, 2008. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff BRENDA MOUNT began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort,

urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

65. Plaintiff DONNA MOYLE is a natural person residing in the State of Georgia. Plaintiff DONNA MOYLE was implanted with an Alyte Mesh device during surgery performed on or around February 12, 2013. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff DONNA MOYLE began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

66. Plaintiff CATHY MYERS is a natural person residing in the State of Missouri. Plaintiff CATHY MYERS was implanted with a Bard Dermis Allograft device during surgery performed on or around January 6, 2003. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff CATHY MYERS began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

67. Plaintiff CHERYL MYERS is a natural person residing in the State of Texas. Plaintiff CHERYL MYERS was implanted with an Align device during surgery performed on or around November 12, 2010. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff CHERYL MYERS began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

68. Plaintiff MARY ALICE NIELSON is a natural person residing in the State of

Missouri. Plaintiff MARY ALICE NIELSON was implanted with an Align device during surgery performed on or around March 1, 2012. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff MARY ALICE NIELSON began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

69. Plaintiff KIMBERLY PETERSON is a natural person residing in the State of Michigan. Plaintiff KIMBERLY PETERSON was implanted with an Align device during surgery performed on or around August 10, 2009. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff KIMBERLY PETERSON began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

70. Plaintiff KATHLEEN PUTORTI is a natural person residing in the State of Florida. Plaintiff KATHLEEN PUTORTI was implanted with a Bard Mesh device during surgery performed on or around June 18, 2009. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff KATHLEEN PUTORTI began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

71. Plaintiff MARY ANN REEVES is a natural person residing in the State of Georgia. Plaintiff MARY ANN REEVES was implanted with a Marlex device during surgery performed on or around May 25, 2011. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them.

After the device was implanted, Plaintiff MARY ANN REEVES began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

72. Plaintiff DOROTHY RESTIVO is a natural person residing in the State of New York. Plaintiff DOROTHY RESTIVO was implanted with an Ajust device during surgery performed on or around Judeuly 13, 2010. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff DOROTHY RESTIVO began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

73. Plaintiff CHERYL RHODES is a natural person residing in the State of Arkansas. Plaintiff CHERYL RHODES was implanted with an Ajust device during surgery performed on or around September 23, 2011. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff CHERYL RHODES began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

74. Plaintiff HILDA RING is a natural person residing in the State of Colorado. Plaintiff HILDA RING was implanted with an Align device during surgery performed on or around November 13, 2007. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff HILDA RING began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries

to remove or part of the pelvic mesh device.

75. Plaintiff FRANCES SANCHEZ is a natural person residing in the State of New Mexico. Plaintiff FRANCES SANCHEZ was implanted with an Align device during surgery performed on or around September 15, 2010. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff FRANCES SANCHEZ began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

76. Plaintiff KATHARINE SESMA is a natural person residing in the State of California. Plaintiff KATHARINE SESMA was implanted with an Align device during surgery performed on or around April 19, 2008. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff KATHARINE SESMA began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

77. Plaintiff CONNIE STANTON is a natural person residing in the State of Missouri. Plaintiff CONNIE STANTON was implanted with an Align device during surgery performed on or around December 13, 2012. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff CONNIE STANTON began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

78. Plaintiff PATRICIA SZEKERES is a natural person residing in the State of Pennsylvania. Plaintiff PATRICIA SZEKERES was implanted with a Bard Mesh device during

surgery performed on or around September 18, 2002. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff PATRICIA SZEKERES began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

79. Plaintiff KIMBERLY TERRY is a natural person residing in the State of Kentucky. Plaintiff KIMBERLY TERRY was implanted with an Align device during surgery performed on or around February 21, 2012. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff KIMBERLY TERRY began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

80. Plaintiff LINDA TIDMORE is a natural person residing in the State of Georgia. Plaintiff LINDA TIDMORE was implanted with an Ajust device during surgery performed on or around November 21, 2011. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff LINDA TIDMORE began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

81. Plaintiff KAREN WEARMOUTH is a natural person residing in the State of North Carolina. Plaintiff KAREN WEARMOUTH was implanted with an Align device during surgery performed on or around October 11, 2012. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff KAREN WEARMOUTH began to

experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

82. Plaintiff HEATHER WELLS is a natural person residing in the State of California. Plaintiff HEATHER WELLS was implanted with an Align device during surgery performed on or around November 26, 2008. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff HEATHER WELLS began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

83. Plaintiff RAINEY WIGGINS is a natural person residing in the State of Texas. Plaintiff RAINEY WIGGINS was implanted with a Bard Mesh device during surgery performed on or around July 21, 2009. The pelvic mesh device was manufactured, marketed, advertised and promoted by Defendants C.R. Bard, Sofradim, TSL, and DOES 1 through 100, and each of them. After the device was implanted, Plaintiff RAINEY WIGGINS began to experience severe complications related to the implant, including but not limited to extreme pain, discomfort, urinary problems, dyspareunia and upon information and believe may have underwent multiple corrective surgeries to remove or part of the pelvic mesh device.

84. As used herein “Implant Plaintiffs” shall mean to refer to the plaintiffs identified herein as someone who was implanted with a Bard transvaginal mesh device.

#### **JURISDICTION AND VENUE**

85. Plaintiffs are informed and believe, and thereon allege that at all times herein mentioned each of the Defendants hereto are individuals, corporations, partnerships and/or unincorporated associations organized and existing under and by virtue of the laws of the State of Missouri , or the laws of some other state or foreign jurisdiction, and that said Defendants, and

each of them, were and are authorized to do and are doing business in the State of Missouri, or the laws of some other state or foreign jurisdiction and that said Defendants have and do regularly conduct business in the State of Missouri.

86. Venue is proper in this county because Plaintiff Deborah Kostedt is a resident of Missouri.

87. Defendant, C.R. Bard, Inc., (“Bard”) is a corporation, organized under the laws of Delaware, with its principle place of business in New Jersey.

88. Bard has its corporate headquarters located at 730 Central Avenue, Murray Hill, New Jersey, and may accept service of process at that location.

### **DEFENDANTS**

89. At all times relevant herein, Defendants were engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, testing, training, marketing, promoting, packaging, labeling, and/or selling such devices, including the Align Urethral Support System, Align TO Urethral Support System, Avaulta Anterior BioSynthetic Support System, Avaulta Posterior BioSynthetic Support System, Avaulta Posterior BioSynthetic Support System, Avaulta Plus Posterior BioSynthetic Support System, Avaulta Solo Anterior Synthetic Support System, Avaulta Solo Posterior Synthetic Support System, InnerLace BioUrethral Support System, Pelvicol Acellular Collagen Matrix, Pelvilace BioUrethral Support, PelviLace TO Trans-obturator BioUrethral Support System, PelviSoft Acellular Collagen BioMesh, the Pelvitex Polypropylen Mesh, Uretex SUP Pubourethral Sling, Uretex SUP Pubourethral Sling, Uretex TO Trans-obturator Urethral Support System, Uretex TO2 Trans-obturator Urethral Support System, and Uretex TO3 Trans-obturator Urethral Support Sytem all hereinafter refereed to as “Pelvic Mesh”

1. At all times alleged herein, Bard includes and included any and all parents, subsidiaries, affiliates, divisions, franchise, partners, joint ventures, and organizational units of any kind, their predecessors, successors, and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

2. At all times alleged herein, Bard conducted regular and sustained business in Missouri by selling and distributing its products in Missouri as described below. By these same activities, Bard has sufficient contacts within the State of Missouri to subject it to the jurisdiction of this Court.

3. The true names and capacities, whether individual, corporate, associate, governmental or otherwise, of defendants named herein as DOES 1 through 100 are unknown to plaintiffs at this time, who therefore sue said defendants by such fictitious names. When the true names and capacities of said defendants have been ascertained, plaintiffs will amend this Complaint accordingly. Plaintiffs are informed and believe, and thereon allege, that each defendant designated as a DOE is responsible, negligently, intentionally, strictly liable or in some other actionable manner, for the events and happenings as alleged herein and are corporations organized and existing under and by virtue of the laws of the State of Missouri, or the laws of some other state or foreign jurisdiction, and that said defendants and each of them were authorized to do and are regularly doing business in the State of Missouri.

4. When referring collectively to all Defendants in this action, Plaintiffs will use the term "Defendants".

#### FACTUAL ALLEGATIONS

12. Defendants' Pelvic Mesh Products contain monofilament polypropylene mesh and/or collagen. Despite claims that polypropylene is inert, the scientific evidence shows that this material as implanted in the relevant female Plaintiff set forth in the Short Form Complaint is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Products. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh. Furthermore, Defendants' collagen products cause hyper-inflammatory responses leading to problems including chronic pain and fibrotic reaction. Defendants' collagen products disintegrate after implantation in the female pelvis. The collagen products cause adverse tissue

reactions, and are causally related to infection, as the collagen is a foreign material derived from animal and/or human tissue. The collagen is harsh upon the female pelvic tissue. When mesh is inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

13. Surgical mesh products have been used to repair abdominal hernias since the 1950s. In the 1970s, gynecologists began using surgical mesh products that were designed for hernia repair for abdominal repair to surgically repair prolapsed organs. In the 1990s, gynecologists began using this surgical mesh for the surgical treatment of POP and SUI. Manufacturers, including Bard, began to modify the mesh used in hernia repair to be used as products specifically intended to correct POP and/or SUI. Today, Bard sells pelvic mesh "kits" which can include not only the surgical mesh, but also tissue fixation anchors and insertion tools. The Products manufactured by Defendants are considered Class II medical devices.

14. Defendants sought and obtained FDA clearance to market the Products under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted by Bard with regard to the Products.

15. On July 13, 2011, the FDA issued a Safety Communication wherein the FDA stated that "serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**" (emphasis in the original).

16. The FDA Safety Communication also stated, "*Mesh contraction* (shrinkage) is a *previously unidentified risk* of transvaginal POP repair with mesh that has been reported in the

published scientific literature and in adverse event reports to the FDA. Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain.” (emphasis in original).

17. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists (ACOG) and the American Urogynecologic Society (AUGS) also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating:

There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh . . . Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

18. The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that “[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk.”

19. The injuries of the female Plaintiff, as will be more fully established in Discovery, are reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion.

20. The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks. Specifically, the FDA Safety Communication stated: “it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk.”

21. Contemporaneously with the Safety Communication, the FDA released a publication titled “Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of

Transvaginal Placement for Pelvic Organ Prolapse” (the White Paper). In the White Paper, the FDA noted that the published, peer-reviewed literature demonstrates that “[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh.”

22. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it “has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk.” (emphasis in original).

23. The FDA White Paper further stated that “these products are associated with serious adverse events . . . compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair.”

24. In its White Paper, the FDA advises doctors to, *inter alia*, “[r]ecognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications.” The FDA concludes its White Paper by stating that it “has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse.”

25. As is known to the Defendants, the risks associated with POP repair are the same as SUI repair. However, the data regarding the magnitude and frequency of these known risks are not as developed as the data on POP repair. The FDA recognized this, as demonstrated by its Section 522 Orders issued to manufacturers of pelvic mesh products used to treat SUI in January of 2012.

26. In September 2011, the FDA acknowledged the need for additional data and noted in “Surgical Mesh For Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence” that the literature and information developing on SUI repair with mesh “indicates that serious complications can occur . . . [and] a case can be made for additional premarket and/or post market studies to better address the risk/benefit of all mesh products used for SUI.”

27. Defendants did not, and have not, adequately studied the extent of the risks associated with the Products. In January 2012, the FDA recognized the risk to women and mandated additional studies to further investigate these risks.

28. Defendant(s) knew or should have known about the Products’ risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

29. Defendants knew or should have known that the Products unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

30. The scientific evidence shows that the material from which the Products are made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Products, including the female Plaintiff named in the Short Form Complaint.

31. This negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced by the female Plaintiff named in the Short Form Complaint.

32. The FDA defines both “degradation” and “fragmentation” as “device problems” to which the FDA assigns a specific “device problem code.” “Material Fragmentation” is defined as an “[i]ssue associated with small pieces of the device breaking off unexpectedly” and “degraded” as an “[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction.” The Products were unreasonably susceptible to degradation and fragmentation inside the body.

33. The Products were unreasonably susceptible to shrinkage and contraction inside the body. Defendants should have known of this serious risk and warned physicians and patients.

34. The Products were unreasonably susceptible to “creep” or the gradual elongation and deformation when subject to prolonged tension inside the body.

35. To this day, the Products have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices, implanted by safe and effective, minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence, and other competing products.

36. A woman who elects to have her SUI or POP surgically treated has several options. SUI can be corrected through traditional abdominal surgery using sutures to attach the urethra to a ligament in the pelvis (known as the “Burch procedure”). SUI can also be surgically addressed using synthetic materials placed under the urethra to provide support. POP can be corrected through abdominal or transvaginal surgery and using biologic, composite, or synthetic materials.

37. Defendants omitted and downplayed the risks, dangers, defects, and disadvantages of the Products, and advertised, promoted, marketed, sold and distributed the

Products as safe medical devices when Defendants knew or should have known that the Products were not safe for their intended purposes, and that the Products would cause, and did cause, serious medical problems. Further, while some of the problems associated with the Products were made known to physicians, the magnitude and frequency of these problems were not disclosed and were hidden from physicians.

38. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, the Products have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiffs.

39. The specific nature of the Products' defects includes, but is not limited to, the following:

- a) The use of polypropylene and collagen in the Products and the immune reactions that result from such material, causing adverse reactions and injuries;
- b) The design of the Products to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;
- c) Biomechanical issues with the design of the Products, including, but not limited to, the propensity of the Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;
- d) The use and design of arms and anchors in the Products, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;
- e) The propensity of the Products for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;
- f) the inelasticity of the Products, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

- g) The propensity of the Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;
- h) The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;
- i) The propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;
- j) The adverse tissue reactions caused by the products, which are causally related to infection, as the mesh is a foreign organic material from animals and/or human cadavers;
- k) The harshness of collagen upon the female pelvic tissue, and the hardening of the product in the body; and
- l) The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

40. The Products are also defective due to Defendants' failure to adequately warn or instruct the female Plaintiff named in the Short Form Complaint and/or her health care providers of subjects including, but not limited to, the following:

- a) The Products' propensities to contract, retract, and/or shrink inside the body;
- b) The Products' propensities for degradation, fragmentation and/or creep;
- c) The Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;
- d) The frequency and manner of mesh erosion or extrusion;
- e) The risk of chronic inflammation resulting from the Products;
- f) The risk of chronic infections resulting from the Products;
- g) The risk of permanent vaginal or pelvic scarring as a result of the Products;
- h) The risk of recurrent, intractable pelvic pain and other pain resulting from the Products;
- i) The need for corrective or revision surgery to adjust or remove the Products;

- j) The severity of complications that could arise as a result of implantation of the Products;
- k) The hazards associated with the Products;
- l) The Products' defects described herein;
- m) Treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible available alternatives;
- n) Treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible available alternatives;
- o) Treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible available alternatives;
- p) Use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;
- q) Removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and
- r) Complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain.

41. Defendants under reported and continues to underreport information about the propensity of the Products to fail and cause injury and complications, and have made unfounded representations regarding the efficacy and safety of the Products through various means and media.

42. Defendants failed to perform proper and adequate testing and research in order to determine and evaluate the nature, magnitude and frequency of the risks attendant to the Products.

43. Defendant(s) failed to design and establish a safe, effective procedure for removal of the Products, or to determine if a safe, effective procedure for removal of the Products exists.

44. Feasible and suitable alternatives to the Products have existed at all times relevant that do not present the same frequency or severity of risks as do the Products.

45. The Products were at all times utilized and implanted in a manner foreseeable to Defendants, as Defendants generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physician.

46. Defendants knowingly provided incomplete and insufficient training and information to physicians regarding the use of the Products and the aftercare of patients implanted with the Products.

47. The Products implanted in the female Plaintiff named in the Short Form Complaint were in the same or substantially similar condition as they were when they left Defendants' possession, and in the condition directed by and expected by Defendants.

48. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Products include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, and chronic pelvic pain.

49. In many cases, including the female Plaintiff named in the Short Form Complaint, women have been forced to undergo extensive medical treatment including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

50. The medical and scientific literature studying the effects of the Products, like that of the product(s) implanted in the relevant female Plaintiff named in the Short Form Complaint,

has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the Products.

51. Removal of contracted, eroded and/or infected mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

52. At all relevant times herein, Defendants continued to promote the Products as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy or safety.

53. In doing so, Defendants failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Products, including the magnitude and frequency of these risks.

53. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put the female Plaintiff named in the Short Form Complaint and the general public on notice of the dangers and adverse effects caused by implantation of the Products.

54. The Products as designed, manufactured, distributed, sold and/or supplied by Defendants were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendants' knowledge of lack of safety.

55. As a result of having the Products implanted in her, the female Plaintiff named in the Short Form Complaint has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further

medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

**FIRST CAUSE OF  
ACTION**

**[Strict Liability – Failure to Warn]**

5. Plaintiffs re-allege and incorporate by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further allege as follows:

6. Defendants manufactured, sold and/or distributed the Pelvic Mesh Products to Plaintiffs to be used for the treatment of stress urinary incontinence and/or pelvic organ prolapse.

7. At all times mentioned herein, the Pelvic Mesh Products were and are, dangerous and presented a substantial danger to patients who were implanted with the Pelvic Mesh Devices, and these risks and dangers were known or knowable at the time of distribution and implantation in Plaintiff. Ordinary consumers would not have recognized the potential risks and dangers the Pelvic Mesh Products posed to pelvic reconstruction patients because its uses was specifically promoted to improve the health of such patients. The Pelvic Mesh Products were used in a way reasonable foreseeable to Defendants by Plaintiffs. Defendants failed to provide warnings of such risks and dangers to Plaintiffs as described herein.

8. As a result of the implantation of the Pelvic Mesh Products Plaintiffs suffered debilitating injuries including extreme pain, erosion, dyspareunia, urinary problems, recurrent incontinence, and for some Plaintiffs the need for additional surgery.

9. In doing the acts herein described, the Defendants acted with oppression, fraud and malice, and Plaintiffs are therefore entitled to punitive damages to deter Defendants and others from engaging in similar conduct in the future. Said wrongful conduct was done with advance knowledge, authorization and/or ratification of an officer, director and/or managing agent of the Defendants.

10. At all times herein mentioned, the Pelvic Mesh Products were being used as intended by Defendants and in a manner foreseeable to Defendants.

11. As a result of the defective condition of the Pelvic Mesh Products, namely the lack of sufficient warnings, Plaintiffs have suffered the injuries and damages alleged herein.

WHEREFORE, said Plaintiffs pray for judgment against Defendants as hereinafter set forth.

**SECOND CAUSE OF  
ACTION**

**[Strict Liability – Manufacturing Defect]**

12. Plaintiffs re-allege and incorporate by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further allege as follows:

13. At all times herein mentioned, Defendants' Pelvic Mesh Products were prescribed and used as intended by Defendants and in a manner reasonably foreseeable to Defendants.

14. The Pelvic Mesh Products were defective at the time of their manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution, and at the time they left the possession of the Defendants, in that, and not by way of limitation, the products differed from the Defendants' intended result and intended design and specifications, and from other ostensibly identical units of the same product line.

15. As a proximate and legal result of the defective condition of the Pelvic Mesh Products, Plaintiffs were caused to suffer and will continue to suffer the herein described injuries and damages.

WHEREFORE, said Plaintiffs pray for judgment against Defendants as hereinafter set forth.

**THIRD CAUSE OF ACTION**

**[Strict Products Liability – Design Defect]**

16. Plaintiffs re-allege and incorporate by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further allege as follows:

17. The Pelvic Mesh Products were designed, engineered, developed, manufactured, fabricated, assembled, equipped, tested or failed to test, inspected or failed to inspect, labeled, advertised, promoted, marketed, supplied, licensed, distributed, wholesaled, and sold by Defendants.

18. The Pelvic Mesh Products manufactured, licensed, supplied, and/or placed into the stream of commerce by Defendants were defective and unreasonably dangerous in that

- a. The foreseeable risks exceeded the benefits associated with the Products design or formulation;
- b. They contained inadequate post-marketing warnings or instructions; and
- c. They were more dangerous than would be expected or appreciated by an ordinary consumer.

19. The Pelvic Mesh Products that were manufactured, supplied, and/or placed into the stream of commerce by Defendants were more dangerous than an ordinary customer would expect, and more dangerous than other Products or procedures available to treat stress urinary incontinence, pelvic organ prolapse and/or rectocele repair.

20. The design defects in Defendants' Products existed at the time when the Products left Defendants' control.

21. Defendants knew that the Products were to be purchased and used without inspection for defects.

22. The Pelvic Mesh Products were and are unsafe for their intended and foreseeable uses by reason of defects in the design so that they would not safely serve its purpose, but would instead expose the users of said Products to incur serious injuries.

23. Plaintiffs used the Products in a reasonably foreseeable manner.

24. Defendants designed the Products defectively, causing them to fail to perform as

safely as an ordinary consumer would expect when used in an intended or reasonably foreseeably manner.

25. As a direct and proximate result of the aforementioned defects in the design of the Products, Plaintiffs sustained the injuries and damages set forth herein.

\WHEREFORE, said Plaintiffs pray for judgment against Defendants as hereinafter set forth.

#### **FOURTH CAUSE OF ACTION**

##### **[Negligence]**

26. Plaintiffs re-allege and incorporate by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further allege as follows:

27. At all times herein mentioned, Defendants, and each of them, were and are engaged in the business of researching, manufacturing, licensing, fabricating, designing, labeling, distributing, using, supplying, selling, marketing, warranting, packaging and advertising the Pelvic Mesh Products.

28. Defendants, and each of them, owed to Plaintiffs and the public a duty to act reasonably and to exercise ordinary care in pursuit of the activities mentioned above, and Defendants, and each of them, breached said duty of due care.

29. At all times relevant hereto, Defendants, and each of them, owed to Plaintiffs and the public a duty to act reasonably and to exercise ordinary care with respect to the safe, legal, and proper manufacture, license, design, formulation, distribution, production, processing, assembly, testing, inspection, research, marketing, labeling, packaging, preparation for use, issuance of warnings with respect to promotion, advertising, sale, and safety monitoring of the Products, and to adequately test and warn of the risk and dangers of the Products, both before and after sale.

30. Additionally, Defendants, and each of them, owed to Plaintiffs and the public a duty to provide accurate, reliable, and completely truthful information regarding the safety and any

dangerous propensities of the Products manufactured, used, distributed, and/or supplied by then and to provide accurate, reliable, and completely truthful information regarding the failure of the Products to perform as intended or as an ordinary consumer would expect.

31. At all times relevant hereto, Defendants, and each of them, singularly and jointly, breached the aforementioned duties in that they negligently and carelessly manufactured, fabricated, designed, licensed, produced, compounded, assembled, inspected or failed to inspect, tested or failed to test, warned or failed to warn of the health hazards, labeled, distributed, handled, used, supplied, sold, marketed, warranted, packaged, promoted and advertised the Pelvic Mesh Products in that said Products caused, directly and proximately, the injuries of Plaintiff through failure of the Products to perform as intended or as an ordinary consumer would expect.

32. The acts of Defendants, and each of them, as herein alleged, constitute violations of the duty of ordinary care and skill owed by Defendants, and each of them, to Plaintiffs.

33. Plaintiffs used, handled, or were implanted with Defendants Products referred herein in a manner that was reasonably foreseeable.

34. As the direct and proximate result of Defendants' breach of their aforementioned duties with respect to the Products, Plaintiffs suffered the injuries and damages alleged herein.

WHEREFORE, said Plaintiffs pray for judgment against Defendants as hereinafter set forth.

#### **FIFTH CAUSE OF ACTION**

#### **[Breach of Implied Warranty]**

35. Plaintiffs re-allege and incorporate by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further allege as follows:

36. Defendants, and each of them, impliedly warranted to the Plaintiffs, their prescribing physicians and healthcare providers, the medical scientific, pharmaceutical and health communities, the FDA, and the public, in general, that the Products were of merchantable quality and safe and fit for the use for which they were intended.

37. Plaintiffs and their physicians and healthcare providers were, and remain, unskilled in the research, design and manufacture of the Products and reasonably relied on the skill, judgment and implied warranty of Defendants in using the aforementioned Products.

38. Defendants breached their warranties in that the Products were neither safe for their intended use nor of merchantable quality, as warranted by Defendants, in that the Products had dangerous propensities and known or knowable side effects when put to their intended use and would cause severe injuries to the user, which propensities and side effects were known or knowable but were not warned of by Defendants.

39. As a result of the aforementioned breach of implied warranties by Defendants and each of them, Plaintiffs suffered injuries and damages as alleged herein.

40. After Plaintiffs were made aware their injuries were a result of the aforesaid Pelvic Mesh Products, Defendants had ample and sufficient notice of breach of said warranty.

WHEREFORE, said Plaintiffs pray for judgment against Defendants as hereinafter set forth.

#### **SIXTH CAUSE OF ACTION**

#### **[Breach of Express Warranty]**

41. Plaintiffs re-allege and incorporate by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further allege as follows:

42. Defendants expressly warranted to Plaintiffs and/or their authorized agents or sales representations, in publications, and other communications intended for medical patients, and the general public, that the defective Pelvic Mesh Products were safe, effective, fit and proper for their intended use.

43. Plaintiffs and Plaintiffs' physicians reasonably relied upon the skill and judgment of Defendants, and upon said express warranty, in using the aforesaid products. The warranty and representations were untrue in that the product caused severe injury to Plaintiffs and was unsafe and, therefore, unsuited for the use in which it was intended and caused Plaintiffs to sustain

damages and injuries herein alleged.

44. As soon as the true nature of the products, and the fact that the warranty and representations were false, were ascertained, said Defendants had ample and sufficient notice of the breach of said warranty.

WHEREFORE, said Plaintiffs pray for judgment against Defendants as hereinafter set forth.

### **SEVENTH CAUSE OF ACTION**

#### **[Negligent Misrepresentation]**

45. Plaintiffs re-allege and incorporate by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further allege as follows:

46. Defendants from the time that the Pelvic Mesh Products were first tested, studied, researched, first manufactured, marketed and distributed, and up to the present, made false representations, as previously set forth herein, to the Plaintiffs, their prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public in general, including, but not limited to, the misrepresentation that the Pelvic Mesh Products were safe, fit, and effective for the treatment of pelvic organ prolapse, stress urinary incontinence, and/or rectocele repair.

47. At all times relevant hereto, Defendants conducted a sales and marketing Campaign to promote the sale of the Pelvic Mesh Products and willfully deceive the Plaintiffs, their prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public in general as to the health risks and consequences of the use of the Pelvic Mesh Products.

48. Defendants made the foregoing misrepresentations without any reasonable ground for believing them to be true. These misrepresentations were made directly by Defendants, by sales representatives, detail persons and other authorized agents of said Defendants, and in publications and other written materials directed to the Plaintiffs, their prescribing physicians and

healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public in general with the intention of inducing reliance and the purchase and implantation of the Pelvic Mesh Products.

49. The foregoing representations by Defendants were in fact false in that the Pelvic Products are not, and at all relevant times alleged herein, were not safe, fit, and effective for the treatment of pelvic organ prolapse, stress urinary incontinence and/or rectocele, the use of the Pelvic Mesh Products is hazardous to health, and the Pelvic Mesh Products have a significant propensity to cause serious injuries to users including, but not limited to, the injuries suffered as described herein. The foregoing misrepresentations by Defendants were made with the intention of inducing reliance and inducing the purchase and implantation of Pelvic Mesh Products.

50. In reliance on the misrepresentations by Defendants, Plaintiffs and their prescribing physicians and healthcare providers were induced to purchase use the Pelvic Mesh Products. If they had known of the true facts and the facts concealed by Defendants, they would not have used the Pelvic Mesh Products, and their reliance upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

51. As a result of the concealment of the facts set forth above, Plaintiffs sustained injuries as set forth herein.

WHEREFORE, said Plaintiffs pray for judgment against Defendants as hereinafter set forth.

### **EIGHT CAUSE OF ACTION**

#### **[Fraud by Concealment]**

52. Plaintiffs re-allege and incorporate by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further allege as follows:

53. At all times mentioned herein, Defendants had the duty and obligations to disclose to Plaintiff and to her physicians, the true facts concerning the Pelvic Mesh Products, that is, that

said products were dangerous and defective, lacking efficacy for their purported use and lacking safety in normal use, and how likely it was to cause serious consequences to users including permanent and debilitating injuries. Defendants made the affirmative representations as set forth above to Plaintiffs and their physicians and the general public prior to the date the Pelvic Mesh Products were implanted in Plaintiffs, while concealing material facts.

54. At all times herein mentioned, Defendants, and each of them, willfully, and maliciously concealed facts as set forth above from Plaintiffs and their physicians, and therefore Plaintiffs, with the intent to defraud as herein alleged.

55. At all times herein mentioned, neither Plaintiffs nor their physicians were aware of the facts set for the above, and had they been aware of said fact, they would not have acted as they did, that is, would not have reasonably relied upon said representations of safety and efficacy and utilized the Pelvic Mesh Products for correction of urinary incontinence, pelvic organ prolapse, vaginal vault prolapse and rectocele. Defendants' misrepresentations were a substantial fact in Plaintiffs utilizing the Pelvic Mesh Products for correction of their medical conditions.

56. As a result of the concealment of the facts set for the above, Plaintiffs sustained injuries as set forth herein.

57. The herein-described conduct of said Defendants, and each of them, was willful, malicious, fraudulent, outrageous and in conscious disregard and indifference to the safety and health of patients with pelvic medical conditions, such as Plaintiffs. Plaintiffs, for the sake of example and by way of punishing said Defendants, seek punitive damages according to proof.

WHEREFORE, said Plaintiffs pray for judgment against Defendants as hereinafter set forth.

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs pray for judgment against Defendants, and each of them, as follows:

1. For past and future general damages, according to proof;

2. For past and future medical and incidental expenses, according to proof;
3. For past and future loss of earnings and/or earning capacity, according to proof;
4. For future medical monitoring costs, according to proof;
5. For punitive and exemplary damages in an amount to be determined at trial;
6. For injunctive relief, enjoining Defendants from the acts of unfair competition and untrue and misleading advertising;
7. For a disgorgement of profits, according to proof.
8. For such other and further relief as the Court may deem just and proper, including costs and prejudgment interest as provided in C.C.P. section 998, C.C.P. section 1032, and related provisions of law.

DATED: January 25, 2019

**NAPOLI SHKOLNIK, PLLC**

By: /s/ Wilson D. Sikes

Wilson D. Sikes (MO Bar # 69579)  
Mark Twain Plaza III  
105 West Vandalia Street, Suite 475  
Edwardsville, IL 62025  
[WSikes@Napolilaw.com](mailto:WSikes@Napolilaw.com)  
**ATTORNEYS FOR PLAINTIFF**